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M E M O R A N D U M

TO: Maine Board of Environmental Protection

FROM: Maine DHHS, Maine CDC

RE: Joint Rulemaking (DHHS & DEP) for Lab Certification Rules

DATE: August 10, 2009

Proposed Rule Amendments to the Maine Comprehensive And Limited Environmental Laboratory Certification Rules, 10-144 CMR 263

22 M.R.S.A. § 567 authorizes both DHHS and DEP to establish rules that govern the lab certification process in Maine. The following summary explains the proposed changes from DHHS, Maine CDC's Lab Certification Officer Matthew Sica.

INTRODUCTION:

Environmental laboratories conduct analyses of our water, soil and other materials. Clients of environmental laboratories include state government entities like the Maine Department of Health and Human Services Center for Disease Control and Prevention ("DHHS") and the Maine Department of Environmental Protection ("DEP"), as well as homeowners, consultants, and commercial entities. Analyses performed by laboratories are often used to determine compliance status with federal, state and local regulations. These analyses have a direct effect upon human health and the environment. Therefore, laboratories are required to employ standardized procedures and methodologies to ensure that environmental data are reliable and accurate.

The Maine Environmental Laboratory Certification Program ("MELCP") was established to help ensure that laboratories are submitting reliable and consistent data to Maine's various environmental programs. The program offers certification designed to accommodate the needs of the Departments' programs that includes testing required by the Safe Drinking Water Act, Lead Poisoning Control Act, Clean Water Act, the Resource Conservation and Recovery Act, and the Maine Leaking Underground Storage Tanks [LUST] Program.

Specifically, 22 MRSA §567 authorizes DHHS Maine CDC to appoint a laboratory certification officer to certify laboratories that test health and environmental samples under DHHS and DEP. Both DHHS and DEP are authorized by this statute to adopt lab certification rules, which include standards for certificate approval, analytical methods and quality assurance methods.

Reliable technical and scientific analyses are essential for making sound decisions necessary for the protection of public health and the environment. Therefore, MELCP developed procedures and requirements for ensuring that laboratories are producing accurate and precise analytical results. Lab certification requires that a laboratory's quality system, staff, facilities, equipment, test methods, records and reports are evaluated, using objective and measurable criteria.

DHHS developed the proposed amendments to the current Laboratory Certification Rules (10-144 CMR 263), with input from stakeholders, and incorporated the standards for quality control adopted by the national conference of states and federal agencies.

What is the Environmental Laboratory Certification Process?

Certification of environmental laboratories typically includes four steps: application, inspection, award of certification, and proof of ongoing proficiency.

The major procedural requirements for each step are as follows:

1. **Application.** A laboratory submits an application, fees and documentation to the MELCP for review.
2. **Inspection.** The MELCP staff conducts an on-site inspection of the facility, when applicable, to ensure compliance with the application materials.
3. **Award of Certification.** A certification is awarded to laboratories that successfully complete the application process. The certification is officially documented with issuance of a certificate and an associated analytes list. The certification consists of two parts:
 - (a) **A Base Certificate** acknowledges that the laboratory holds the policies, procedures and equipment necessary to produce reliable data; and
 - (b) **A Program Analyte List** is a list of all analyte-method-matrix-test-category (fields of testing) combinations (on the scope of certification) that the laboratory is authorized to analyze, due to meeting the minimum requirements specified in these rules.
4. **Ongoing Proficiency.** Laboratories certified by MELCP must continue to demonstrate the capability to produce reliable environmental data.

Laboratories must implement a quality system that identifies potential areas of noncompliance. In identifying areas of risk and proposing quality controls to mitigate these risks, the laboratory's implementation of the quality system is performance-based. Should errors occur too frequently or remain undetected, the laboratory is expected to modify its processes to ensure that such events are prevented, rather than solely corrective in nature.

Part of the quality system must include the analysis of proficiency testing samples. Laboratories obtain and analyze standardized samples that have qualitative and quantitative values known only to the provider. The proficiency testing provider publishes the identity and concentration of the sample after a specified date, thereby allowing all parties to review the accuracy of their processes.

Laboratories are subject to these and other ongoing requirements to ensure that their operations are consistent with the certification rules. Failure to maintain compliance with the rules for certification may require enforcement action by DHHS. These enforcement actions for laboratory certification are limited to suspension or revocation of an existing certification and denial of certification for initial or renewal applicants. Currently, DHHS does not have statutory authority to levy fines for noncompliance with these rules.

Why are rule changes being proposed?

The MELCP is considering rule amendments to assure a high standard for the quality of data produced by laboratories engaged in environmental testing and to further clarify the intent of the current ***Maine Comprehensive And Limited Environmental Laboratory Certification Rules, 10-144 CMR 263***. Adoption of these rule amendments will ensure that Maine rules for laboratory certification are consistent with those of other states. A consistent approach to regulation of laboratories allows meaningful exchange of laboratory information between states, as well as in reporting to federal agencies. A rule consistent with national standards also allows laboratories certified by multiple states to more easily interpret the regulation and achieve compliance.

What are the major changes proposed for Comprehensive And Limited Environmental Laboratory Certification Rules, 10-144 CMR 263?

The major changes proposed within these lab certification rules include the following:

- (1) **Updated and Increased Definitions.** The proposed amendments incorporate more definitions to ensure consistency in the use of terminology. Other terminology has been updated to reflect current usage within the environmental testing industry. For example, the term “performance evaluation” is obsolete and has been replaced by the term “proficiency testing”;
- (2) **Incorporation of Current Policies and National Standards.** The proposed amendments define a consistent set of rules for the administration of the environmental laboratory review process. This update is intended to assist regulated parties to achieve compliance by incorporating several existing industry standards, along with current MELCP rules and policies. The rules also incorporate detail from existing guidance documents, which include the following:
 - Incorporation of Quality System elements, the 2003 National Environmental Laboratory Accreditation Conference NELAC standard and the International Organization for Standardization / International Electrotechnical Commission, ISO/IEC 17025:1999;
 - Allowance for performance-based methods and method flexibility, where applicable by program; and
 - Updated use of new methods.
- (3) **Proficiency Testing Requirements.** With these proposed changes, DHHS also amended the proficiency testing requirements for laboratories and proficiency test providers. Laboratories will be required to perform one proficiency test per year instead of the current rule’s requirement for two tests. The NELAC Institute’s (TNI) PT Board reviewed statistical data, which showed only a small increase of laboratory effectiveness, if two PTs per year occurred, compared to one PT per year. This study analyzed the pass/fail data for PT

sample data sets for laboratories performing two PT samples per year and other laboratories performing one PT sample per year. This change would realize a cost savings to the laboratories, without detriment to quality;

- (4) **On-site Inspections.** DHHS proposes to amend the manner in which on-site inspections are conducted. Currently, a laboratory located in Maine could receive NELAC accreditation from another state and be exempted from the biennial onsite inspection of the MELCP. This practice limited the effectiveness of the MELCP on regulating these particular laboratories, whereas this change would require laboratories located in Maine to be inspected by the MELCP. If adopted, this change would require the MELCP to perform out-of-state laboratory inspections when the resident state's inspections are performed at a frequency of greater than two years. The MELCP would perform inspections for all of its programs, including the MEDRO/GRO program for the DEP Leaking Underground Storage Tanks [LUST] Program. Current rule does not require inspections for this program; and
- (5) **Re-organization of the existing rules.** With this proposed rule change, DHHS amended the organization of the rules themselves, in order to reflect the general sequence of the certification process, which promotes clarity and helps achieve compliance.